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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,402	02/15/2001	Pericles Calias	5007	2991

24536 7590 06/28/2002

GENZYME CORPORATION  
LEGAL DEPARTMENT  
15 PLEASANT ST CONNECTOR  
FRAMINGHAM, MA 01701-9322

EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/784402

Applicant(s)

Calias et al

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 2/5/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-54 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-54 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Claims in the application are 1-54.

Restriction to one of the following inventions is required under 35  
U.S.C. 121:

- I. Claims 1-14 and 45-54, drawn to a biologically active conjugate  
of a biopolymer and a therapeutic agent, pharmaceutical  
composition containing the conjugate and method of  
administering the pharmaceutical composition to a subject,  
classified in class 424, subclass 94.61.
- II. Claims 15-28, drawn to a method of preparing a biologically  
active conjugate of a biopolymer and a therapeutic agent,  
classified in class 435, subclass 177.
- III. Claims 29-44, drawn to a chemically modified biopolymer,  
classified in class 536, subclass 1.11.

The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product  
made. The inventions are distinct if either or both of the following can  
be shown: (1) that the process as claimed can be used to make other and  
materially different product or (2) that the product as claimed can be  
made by another and materially different process (MPEP § 806.05(f)). In  
the instant case the product (conjugate) can be produced by a materially  
different process. For example, the product can be prepared by reacting  
a therapeutic agent having a thiol group with a spacer having a thiol  
group to form a disulfide bond coupling the therapeutic agent to the  
spacer, and then coupling the resultant product to the biopolymer.

The chemically modified biopolymer of invention III is produced by a method different than required by invention II since the chemically modified biopolymer does not require a conjugate with a therapeutic agent, and the chemically modified biopolymer can have uses other than to  
5 conjugate with a therapeutic agent as required in inventions I and II. For example, the chemically modified biopolymer can be used as a support for culturing microorganisms, or for enzyme immobilization to carry out enzymatic reactions not related to conjugating with a therapeutic agent. Additionally, inventions I and II can be performed without using a  
10 chemically modified biopolymer as required by the invention of III. For example, the spacer can be coupled to the therapeutic agent, and this product then coupled to the biopolymer without prior chemically modifying the biopolymer.

Because these inventions are distinct for the reasons given above  
15 and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even  
20 though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application.

Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone  
5 number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

15 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1245/